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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,922

09/05/2003

Jose Luis Moctezuma de la Barrera

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,922	Applicant(s) MOCTEZUMA DE LA BARRERA ET AL.	
	Examiner david shay	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 12, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,28-53,89-99,101,103-106 and 123-148 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,28-53,89-99,101,103-106 and 123-148 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>May 12, 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed May 12, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “wherein the three-dimensional model is not compared to a scan”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 136 and 148 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on wherein the three-dimensional model is not compared to a scan.

Claims 1-12, 14-26, 28-39, 41-53, 89-99, 101, 103- 106, and 133-148 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al in combination with Dance, DiGioia et al (NPL) and Kienzle, III et al. Carson et al teach a method as claimed except for any discussion of the placement of the stem and use of the sagittal and coronal planes. Dance et al teach the instant method of locating the positions of the joints. DiGioia et al (NPL) teach a method as claimed except for the specific recitation of producing a three-dimensional model of the joint per se, however a simulation of the determination of the range of motion of the implant is discussed at page 11, with respect to figure 3, this is considered to be sufficient for performing a

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simulation, which is considered to be a “virtual trial” as claimed. Kienzle, III et al teach performing all aspects of the surgery as a simulation prior to actually performing the operation. It would have been obvious to the artisan of ordinary skill to provide the method of DiGioia et al (NPL) in the method of Carson et al, since this will provide a better fit and reduce the incidences of dislocations, as taught by DiGioia et al (NPL) or alternatively to include the three-dimensional rendering of the joint in of Carson et al in the method of DiGioia et al (NPL), since this would enable the more efficient and realistic determination of and visualization of the appropriate placement of the portions of the implant, and in either case, to employ the method of Dance et al to locate the anatomical landmarks such as the center of rotation of the joint, since this is a necessary part of properly fitting a hip prosthesis, and further, in either case to provide a simulation of all aspects of the surgery, prior to performing it, since this will assure the optimum outcome for the patient, by exposing any problems with joint positioning before the bones are actually cut, and still further in either case to record the various anatomical landmarks recited, to provide the various axes etc, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, thus producing a method such as claimed.

Claims 13 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al in combination with Dance et al, DiGioia et al (NPL), and Kienzle, III et al as applied to claims 1-12, 14-26, 28-39, 41-53, 89-99, 101, and 103-106 above, and further in view of Gustilo et al. Gustilo et al teach that relating the depth of the reaming to the depth of the medial wall maximizes the stability of the prosthesis. It would have been obvious to the artisan of ordinary skill to relate the depth of the reaming to the depth of the medial wall in the combined methods

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of Carson et al, Dance et al, and DiGioia et al (NPL) maximizes the stability of the prosthesis, as taught by Gustilo et al, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-26, 28-53, 89-99, 101, and 103-106 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-46 of copending Application No. 10/732,553. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a

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second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-26, 28-53, 89-99, 101, and 103-106 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-35 of copending Application No. 11/148,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection.

Applicant's arguments with respect to claims 1-26, 28-53, 89-99, 101, and 103-106 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3735